

16, and 30-33 are now in application. Consideration and allowance of these claims as now presented is respectfully requested.

**Rejection of Claims Under 35 U.S.C. §102**

Claims 1-3, 5, 7 and 16 stand rejected under 35 U.S.C. §102(a) as being anticipated by Hewlett Healthcare Limited WO98/51300. The Hewlett WO98/51300 is not available as prior art against the present application. The present United States national application is a national phase filing of PCT Application No. PCT/GB99/03731. The PCT application from which the present national phase application was spawned itself claims priority from British patent application serial no. 9824604.4, filed November 11, 1998. Copies of relevant application papers claiming priority from British application no. 9824604.4 are enclosed herewith. A new Declaration for the present application in compliance with 37 CFR §1.67(a) reflecting the correct chain of priority is currently awaiting execution by the inventor. The new executed Declaration will be forwarded to the U.S. PTO as soon as possible.

The effective filing date of the present application, therefore, is the filing date of British application 9824604.4, which is November 11, 1998. 35 U.S.C. §365(b) provides that an international application designating the

United States shall be entitled to the right of priority of a prior foreign application, which may be another international application or a regularly filed foreign application. Section 365(b) of Title 35 U.S.C. applies to the present application, as it is a national phase application of an international application designating the United States. Therefore, the effective filing date of the present application for right of priority is November 11, 1998.

The Hewlett WO98/51300 reference was filed by the same Applicant as in the present application, and was published on December 2, 1998. According to the conditions for patentability set forth in 35 U.S.C. §102, a patent or other printed publication that is not published prior to the date of invention of the present application does not act as prior art thereagainst. As a result, the asserted claim rejections under 35 U.S.C. §102(a) are inoperative and should accordingly be withdrawn.

Even if the asserted claim rejections were operative, the cited prior art fails to teach or disclose the invention as presently claimed. The presently pending claims recite a composition that is formulated such that at least 15% of the chromone dissolves within 10 minutes of exposure to intestinal fluid. Nowhere does Hewlett

WO98/51300 disclose a formulation capable of such quick dissolution in intestinal fluid. It is a primary object of the present invention to enable relatively expedient chromone dissolution in intestinal fluids, and particularly substantially within 10 minutes of exposure to such intestinal fluids. The claimed and desired rate of chromone dissolution is enabled by the particular formulation of the composition of the present invention, which formulation is novel thereto. In other words, neither Hewlett WO98/51300, nor any other cited art, teach or disclose the present formulation enabling the claimed chromone dissolution rate in intestinal fluid. Such an increase rate of chromone dissolution provided by the composition of the present invention results in enhanced effectiveness against allergic reactions. Therefore, even if the asserted claim rejections were operative, such rejections should accordingly be withdrawn.

Claims 1-3, 5, 7, and 16 stand rejected under 35 U.S.C. §102(a) as being anticipated by Wigmore (GB 2,324,962). Wigmore '962 has the same applicant as in the present application, and has a publication date of November 11, 1998. In light of the above, Wigmore '962 is inoperative as prior art against the present application.

Even if Wigmore '962 was operative, no teaching or disclosure of the compositions as presently claimed are found therein. Wigmore '962 fails for the same reasons as applied against the Hewlett WO98/51300 reference. Accordingly, the claim rejections based thereon should be withdrawn.

**Rejection of Claims Under 35 U.S.C. §103**

Claims 1-5, 7 and 16 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Hewlett WO98/51300 and Wigmore '962. As stated above, neither Hewlett WO98/51300 more Wigmore '962 are operative as prior art against the present application. Moreover, neither Hewlett WO98/51300 more Wigmore '962 teach or suggest the claimed chromone dissolution rate that is enabled by the novel formulations of the present invention. As such, the claim rejections under 35 U.S.C. §103 should accordingly be withdrawn.

Claims 6, 8, and 9 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Hewlett WO98/51300, Wigmore '962, and Pharmacia AB (WO85/00015). The Pharmacia reference generally discloses an anti-allergic tablet that is resistant to gastric fluids. Nowhere does Pharmacia teach or suggest a composition specifically formulated for rapid chromone dissolution and uptake into the biosystem as is presently claimed. As stated on pages 13-15, for

relatively large mass of disintegrant with respect to the chromone. Such a relatively large mass of disintegrant material in the composition allows rapid disintegration of the tablet or other physical form before a chromone gel is able to form, which chromone gel acts to slow chromone dissolution and uptake. To obtain an expedient and consistent chromone dissolution, therefore, a relatively high concentration of disintegrant in the composition is desired. As a result, the presently pending claims recite a ratio of at least 1.4:1 of disintegrant to chromone.

The rapid chromone dissolution presently claimed is therefore facilitated by specific disintegrant ratios that enable tablet dissolution in intestinal fluids while acting to prevent the formation of deleterious chromone gel. Disintegrant to chromone ratios significantly less than those claimed can have the effect of allowing a chromone gel to form upon exposure to intestinal fluids (see page 17 lines 10-23). Nowhere does Pharmacia teach or suggest such specific disintegrant to chromone ratios as described and claimed in the present invention. As such, the compositions of Pharmacia do not reflect the desired rapid chromone dissolution that is presently claimed. Thus, the asserted claim rejections under 35 U.S.C. §103 should accordingly be withdrawn.

asserted claim rejections under 35 U.S.C. §103 should accordingly be withdrawn.

For the foregoing reasons, the claims as presently amended are believed to be unobvious and patentable over the cited prior art, whether taken alone or in combination. Applicant therefore submits that the claims as currently presented are allowable on the merits. An early allowance is respectfully solicited.

Respectfully submitted,

HAUGEN LAW FIRM PLLP

A handwritten signature in black ink, appearing to read 'Mark J. Burns', is written over the printed name.

Mark J. Burns, Reg. #46591  
Attorney for Applicant  
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Version with Marking to Show Changes Made

In the Title

Please change the title to read "CHROMONE ENTERIC  
RELEASE FORMULATION".

In the Specification

Please add the following text as a new page 65 of the  
application having a page heading "Abstract of the  
Disclosure".

Orally administered chromones have been found to be  
effective in the treatment of allergic conditions such as  
asthma, general food allergies, ulcerative colitis, atopic  
eczema, chronic urticaria, and irritable bowel syndrome if  
it is presented such that the respective chromone becomes  
bioavailable within ten minutes of exposure to an  
intestinal fluid.

In the Claims

Please withdraw Claims 10-15 and 17-29 from present  
consideration, but with right of reintroduction being  
maintained.

Please amend Claims 6, 8, and 16 as follows.

6. A composition according to any of the preceding  
claims wherein the composition further comprises  
disintegrant at a ratio of at least [1.2:1] 1.4:1(w:w) of  
disintegrant to chromone.

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8. An oral drug delivery composition comprising a chromone wherein the composition further comprises disintegrant at a ratio of at least [1.2:1] 1.4:1 (w:w) of disintegrant to chromone.

16. A composition according to any one of claims 6, 8, or 9[, 11, 13] wherein the disintegrant is microcrystalline cellulose.

Please add new claims 30-33 as follows.

30. A composition according to any of the preceding claims further comprising an amphoteric surfactant or a surfactant having a hydrophile-lipophile balance (HLB) value of less than about 10.

31. A composition according to claim 7 or 10 wherein the pellets are melt pellets.

32. A composition according to any one of claims 7 or 31 wherein the pellets have a diameter of between 0.7mm and 1.8mm.

33. A composition according to any one of the preceding claims wherein the chromone is sodium cromoglycate.





CERTIFICATE OF MAILING

I hereby certify that the foregoing Amendment in application Serial No. 09/831,681, filed May 10, 2001 of Alexander James Wigmore, entitled "CHROMONE ENTERIC RELEASE FORMULATION" along with a transmittal cover letter are being deposited with the United States Postal Service as First Class mail, postage prepaid, in an envelope addressed to: The Commissioner of Patents and Trademarks, Washington, D. C. 20231, on this 9<sup>th</sup> day of December, 2002.

A handwritten signature in cursive script, reading "Denise L. Siede".

Denise L. Siede  
Secretary to Mark J. Burns  
Attorney for Applicants

Date of Signature: Dec. 9, 2002



Sheet No. 2.

International application No.  
PC17GB99/03731**Box No. III AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE**The following person is ☒ agent ☐ common representativeand ☒ has been appointed earlier and represents the applicant(s) also for international preliminary examination.☐ is hereby appointed and any earlier appointment of (an) agent(s)/common representative is hereby revoked.☐ is hereby appointed, specifically for the procedure before the International Preliminary Examining Authority, in addition to the agent(s)/common representative appointed earlier.Name and address: (Family name followed by given name; for a legal entity, full official designation.  
The address must include postal code and name of country.)

**BASSETT, Richard S**  
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37540 Potter G

☐ Address for correspondence: Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.**Box No. IV BASIS FOR INTERNATIONAL PRELIMINARY EXAMINATION****Statement concerning amendments:\***

1. The applicant wishes the international preliminary examination to start on the basis of:

☒ the international application as originally filedthe description ☐ as originally filed☐ as amended under Article 34the claims ☐ as originally filed☐ as amended under Article 19 (together with any accompanying statement)☐ as amended under Article 34the drawings ☐ as originally filed☐ as amended under Article 342. ☐ The applicant wishes any amendment to the claims under Article 19 to be considered as reversed.3. ☐ The applicant wishes the start of the international preliminary examination to be postponed until the expiration of 20 months from the priority date unless the International Preliminary Examining Authority receives a copy of any amendments made under Article 19 or a notice from the applicant that he does not wish to make such amendments (Rule 69.1(d)). (This check-box may be marked only where the time limit under Article 19 has not yet expired.)

\* Where no check-box is marked, international preliminary examination will start on the basis of the international application as originally filed or, where a copy of amendments to the claims under Article 19 and/or amendments of the international application under Article 34 are received by the International Preliminary Examining Authority before it has begun to draw up a written opinion or the international preliminary examination report, as so amended.

Language for the purposes of international preliminary examination: English☒ which is the language in which the international application was filed.☐ which is the language of a translation furnished for the purposes of international search.☐ which is the language of publication of the international application.☐ which is the language of the translation (to be) furnished for the purposes of international preliminary examination.**Box No. V ELECTION OF STATES**

The applicant hereby elects all eligible States (that is, all States which have been designated and which are bound by Chapter II of the PCT)

excluding the following States which the applicant wishes not to elect:

Sheet No. ...3

International application No.  
PCT/GB99/03731**Box No. VI CHECK LIST**

The demand is accompanied by the following elements, in the language referred to in Box No. IV, for the purposes of international preliminary examination:

- |                                                                          |   |        |
|--------------------------------------------------------------------------|---|--------|
| 1. translation of international application                              | : | sheets |
| 2. amendments under Article 34                                           | : | sheets |
| 3. copy (or, where required, translation) of amendments under Article 19 | : | sheets |
| 4. copy (or, where required, translation) of statement under Article 19  | : | sheets |
| 5. letter                                                                | : | sheets |
| 6. other (specify)                                                       | : | sheets |

For International Preliminary  
Examining Authority use only

received      not received

<input type="checkbox"/>	<input type="checkbox"/>
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The demand is also accompanied by the item(s) marked below:

- |                                                                                                     |                                                                                                     |
|-----------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------------------|
| 1. <input checked="" type="checkbox"/> fee calculation sheet                                        | 4. <input type="checkbox"/> statement explaining lack of signature                                  |
| 2. <input type="checkbox"/> separate signed power of attorney                                       | 5. <input type="checkbox"/> nucleotide and/or amino acid sequence listing in computer readable form |
| 3. <input checked="" type="checkbox"/> copy of general power of attorney; reference number, if any: | 6. <input type="checkbox"/> other (specify):                                                        |

**Box No. VII SIGNATURE OF APPLICANT, AGENT OR COMMON REPRESENTATIVE**

Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the demand).



Richard Bassett

For International Preliminary Examining Authority use only

1. Date of actual receipt of DEMAND:

2. Adjusted date of receipt of demand due to CORRECTIONS under Rule 60.1(b):

3. ☐ The date of receipt of the demand is AFTER the expiration of 19 months from the priority date and item 4 or 5, below, does not apply.

☐ The applicant has been informed accordingly.

4. ☐ The date of receipt of the demand is WITHIN the period of 19 months from the priority date as extended by virtue of Rule 80.5.

5. ☐ Although the date of receipt of the demand is after the expiration of 19 months from the priority date, the delay in arrival is EXCUSED pursuant to Rule 82.

For International Bureau use only

Demand received from IPEA on:

## CHAPTER II

## PCT

## FEE CALCULATION SHEET

Annex to the Demand for international preliminary examination

International application No. <b>PCT/GB99/03731</b>	For International Preliminary Examining Authority use only								
Applicant's or agent's file reference <b>HEWY/P21824PC</b>	Date stamp of the IPEA								
Applicant <b>Hewlett Healthcare Limited, et al</b>									
<b>Calculation of prescribed fees</b>									
1. Preliminary examination fee .....	<div style="border: 1px solid black; padding: 2px; display: inline-block;">1533 Euro</div> <div style="border: 1px solid black; padding: 2px; display: inline-block; margin-left: 10px;">P</div>								
2. Handling fee <i>(Applicants from certain States are entitled to a reduction of 75% of the handling fee. Where the applicant is (or all applicants are) so entitled, the amount to be entered at H is 25% of the handling fee.)</i> .....	<div style="border: 1px solid black; padding: 2px; display: inline-block;">148 Euro</div> <div style="border: 1px solid black; padding: 2px; display: inline-block; margin-left: 10px;">H</div>								
3. Total of prescribed fees Add the amounts entered at P and H and enter total in the TOTAL box .....	<div style="border: 1px solid black; padding: 2px; display: inline-block;">1681 Euro</div> <div style="border: 1px solid black; padding: 2px; display: inline-block; margin-left: 10px;">TOTAL</div>								
<b>Mode of Payment</b>									
<table style="width: 100%;"> <tr> <td><input type="checkbox"/> authorization to charge deposit account with the IPEA (see below)</td> <td><input type="checkbox"/> cash</td> </tr> <tr> <td><input type="checkbox"/> cheque</td> <td><input type="checkbox"/> revenue stamps</td> </tr> <tr> <td><input type="checkbox"/> postal money order</td> <td><input type="checkbox"/> coupons</td> </tr> <tr> <td><input type="checkbox"/> bank draft</td> <td><input type="checkbox"/> other (specify):</td> </tr> </table>		<input type="checkbox"/> authorization to charge deposit account with the IPEA (see below)	<input type="checkbox"/> cash	<input type="checkbox"/> cheque	<input type="checkbox"/> revenue stamps	<input type="checkbox"/> postal money order	<input type="checkbox"/> coupons	<input type="checkbox"/> bank draft	<input type="checkbox"/> other (specify):
<input type="checkbox"/> authorization to charge deposit account with the IPEA (see below)	<input type="checkbox"/> cash								
<input type="checkbox"/> cheque	<input type="checkbox"/> revenue stamps								
<input type="checkbox"/> postal money order	<input type="checkbox"/> coupons								
<input type="checkbox"/> bank draft	<input type="checkbox"/> other (specify):								
<b>Deposit Account Authorization</b> <i>(this mode of payment may not be available at all IPEAs)</i>  The IPEA/ _____ <input type="checkbox"/> is hereby authorized to charge the total fees indicated above to my deposit account.  <input type="checkbox"/> <i>(this check-box may be marked only if the conditions for deposit accounts of the IPEA so permit)</i> is hereby authorized to charge any deficiency or credit any overpayment in the total fees indicated above to my deposit account.									
Deposit Account Number _____	Date (day/month/year) _____								
Signature _____									

PCT

## REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

for receiving Office use only

International Application No.

International Filing Date.

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference  
(if desired) (12 characters maximum) HEWF / P21824PC

Box No. I	TITLE OF INVENTION	
	TREATMENT OF ALLERGIC CONDITIONS	
Box No. II	APPLICANT	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.) Hewlett Healthcare Limited Yew Turn 7 Church Lane Lockington Derby, DE74 2TF United Kingdom		<input type="checkbox"/> This person is also inventor.  Telephone No. 01509 670215  Facsimile No.  Teleprinter No.
State (that is, country) of nationality: GB		State (that is, country) of residence: GB
This person is applicant for the purposes of: <input type="checkbox"/> all designated States <input checked="" type="checkbox"/> all designated States except the United States of America <input type="checkbox"/> the United States of America only <input type="checkbox"/> the States indicated in the Supplemental Box		
Box No. III	FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.) WIGMORE, Alexander James Yew Turn 7 Church Lane Lockington Derby, DE74 2TF United Kingdom		This person is:  <input type="checkbox"/> applicant only <input checked="" type="checkbox"/> applicant and inventor <input type="checkbox"/> inventor only (if this check-box is marked, do not fill in below.)
State (that is, country) of nationality: GB		State (that is, country) of residence: GB
This person is applicant for the purposes of: <input type="checkbox"/> all designated States <input type="checkbox"/> all designated States except the United States of America <input checked="" type="checkbox"/> the United States of America only <input type="checkbox"/> the States indicated in the Supplemental Box		
<input type="checkbox"/> Further applicants and/or (further) inventors are indicated on a continuation sheet.		
Box No. IV	AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE	
The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as: <input checked="" type="checkbox"/> agent <input type="checkbox"/> common representative		
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.) Bassett, Richard S Eric Potter Clarkson Park View House 58 The Ropewalk Nottingham. NG1 5DD England		Telephone No. (0115) 9552211  Facsimile No. (0115) 9552201  Teleprinter No. 37540 Potter G
<input type="checkbox"/> Address for correspondence: Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.		

**Box No.V DESIGNATION OF STATES**

The following designations are hereby made under Rule 4.9(a) (mark the applicable check-boxes; at least one must be marked):  
Regional Patent

- ☒ AP ARIPO Patent: GH Ghana, GM Gambia, KE Kenya, LS Lesotho, MW Malawi, SD Sudan, SZ Swaziland, UG Uganda, ZW Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT
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- ☒ OA OAPI Patent: BF Burkina Faso, BJ Benin, CF Central African Republic, CG Congo, CI Côte d'Ivoire, CM Cameroon, GA Gabon, GN Guinea, GW Guinea-Bissau, ML Mali, MR Mauritania, NE Niger, SN Senegal, TD Chad, TG Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT (if other kind of protection or treatment desired, specify on dotted line) .....

National Patent (if other kind of protection or treatment desired, specify on dotted line):

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| <input checked="" type="checkbox"/> AE United Arab Emirates                        | <input checked="" type="checkbox"/> LR Liberia                                         |
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| <input checked="" type="checkbox"/> AM Armenia .....                               | <input checked="" type="checkbox"/> LT Lithuania .....                                 |
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| <input checked="" type="checkbox"/> KR Republic of Korea .....                     |                                                                                        |
| <input checked="" type="checkbox"/> KZ Kazakhstan .....                            |                                                                                        |
| <input checked="" type="checkbox"/> LC Saint Lucia                                 | <input checked="" type="checkbox"/> CR Costa Rica .....                                |
| <input checked="" type="checkbox"/> LK Sri Lanka                                   | <input checked="" type="checkbox"/> DM Dominica .....                                  |
|                                                                                    | <input checked="" type="checkbox"/> MA Morocco .....                                   |
|                                                                                    | <input checked="" type="checkbox"/> TZ Tanzania .....                                  |

Check-boxes reserved for designating States which have become party to the PCT after issuance of this sheet:


**Precautionary Designation Statement:** In addition to the designations made above, the applicant also makes under Rule 4.9(b) all other designations which would be permitted under the PCT except any designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. (Confirmation of a designation consists of the filing of a notice specifying that designation and the payment of the designation and confirmation fees. Confirmation must reach the receiving Office within the 15-month time limit.)

<b>Box No. VI PRIORITY CLAIM</b>		<input type="checkbox"/> Further priority claims are indicated in the Supplemental Box.		
Filing date of earlier application (day/month/year)	Number of earlier application	Where earlier application is:		
		National application: Country	regional application:* regional Office	international application: receiving Office
item (1) 11/11/1998	9824604.4	GB		
item (2)				
item (3)				
<input checked="" type="checkbox"/> The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) (only if the earlier application was filed with the Office which for the purposes of the present international application is the receiving Office) identified above as item(s): (1)				
<small>* Where the earlier application is an ARIPO application, it is mandatory to indicate in the Supplemental Box at least one country party to the Paris Convention for the Protection of Industrial Property for which that earlier application was filed (Rule 4.10(b)(ii)). See Supplemental Box.</small>				
<b>Box No. VII INTERNATIONAL SEARCHING AUTHORITY</b>				
<b>Choice of International Searching Authority (ISA)</b> <small>(if two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used):</small> ISA /		<b>Request to use results of earlier search; reference to that search (if an earlier search has been carried out by or requested from the International Searching Authority):</b>  Date (day/month/year)      Number      Country (or regional Office)		
<b>Box No. VIII CHECK LIST; LANGUAGE OF FILING</b>				
This international application contains the following number of sheets:  request : 3 description (excluding sequence listing part) : 59 claims : 5 abstract : 1 drawings : 0 sequence listing part of description : 0 <b>Total number of sheets : 68</b>		This international application is accompanied by the item(s) marked below:  1. <input checked="" type="checkbox"/> fee calculation sheet 2. <input type="checkbox"/> separate signed power of attorney 3. <input checked="" type="checkbox"/> copy of general power of attorney; reference number, if any: 4. <input type="checkbox"/> statement explaining lack of signature 5. <input type="checkbox"/> priority document(s) identified in Box No. VI as item(s): 6. <input type="checkbox"/> translation of international application into (language): 7. <input type="checkbox"/> separate indications concerning deposited microorganism or other biological material 8. <input type="checkbox"/> nucleotide and/or amino acid sequence listing in computer readable form 9. <input checked="" type="checkbox"/> other (specify): Form 23/77		
Figure of the drawings which should accompany the abstract:		Language of filing of the International application: English		
<b>Box No. IX SIGNATURE OF APPLICANT OR AGENT</b>				
<small>Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).</small>				
Richard S Bassett				

For receiving Office use only			
1. Date of actual receipt of the purported international application:  3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:  4. Date of timely receipt of the required corrections under PCT Article 11(2):  5. International Searching Authority (if two or more are competent): ISA /	2. Drawings:  <input type="checkbox"/> received:  <input type="checkbox"/> not received:  6. <input type="checkbox"/> Transmittal of search copy delayed until search fee is paid.		
For International Bureau use only			
Date of receipt of the record copy by the International Bureau:			



FORM PTO-1190 (REV 12-29-99)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTORNEY'S DOCKET NUMBER 2001-0878.ORI	
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371				U.S. APPLICATION NO. (If known, see 37 CFR 1.5)	
INTERNATIONAL APPLICATION NO. PCT/GB99/03731		INTERNATIONAL FILING DATE 9 November 1999		PRIORITY DATE CLAIMED 11 November 1998	
TITLE OF INVENTION TREATMENT OF ALLERGIC CONDITIONS					
APPLICANT(S) FOR DO/EO/US Hewlett Healthcare Limited					
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:					
<p>1. <input checked="" type="checkbox"/> This is a <b>FIRST</b> submission of items concerning a filing under 35 U.S.C. 371.</p> <p>2. <input type="checkbox"/> This is a <b>SECOND</b> or <b>SUBSEQUENT</b> submission of items concerning a filing under 35 U.S.C. 371.</p> <p>3. <input checked="" type="checkbox"/> This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the applicable time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).</p> <p>4. <input type="checkbox"/> A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.</p> <p>5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2))</p> <p>a. <input checked="" type="checkbox"/> is transmitted herewith (required only if not transmitted by the International Bureau).</p> <p>b. <input type="checkbox"/> has been transmitted by the International Bureau.</p> <p>c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US).</p> <p>6. <input checked="" type="checkbox"/> A translation of the International Application into English (35 U.S.C. 371(c)(2)).</p> <p>7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))</p> <p>a. <input type="checkbox"/> are transmitted herewith (required only if not transmitted by the International Bureau).</p> <p>b. <input type="checkbox"/> have been transmitted by the International Bureau.</p> <p>c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired.</p> <p>d. <input type="checkbox"/> have not been made and will not be made.</p> <p>8. <input type="checkbox"/> A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).</p> <p>9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).</p> <p>10. <input checked="" type="checkbox"/> A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).</p> <p>Items 11. to 16. below concern document(s) or information included:</p> <p>11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98.</p> <p>12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.</p> <p>13. <input type="checkbox"/> A <b>FIRST</b> preliminary amendment.</p> <p><input type="checkbox"/> A <b>SECOND</b> or <b>SUBSEQUENT</b> preliminary amendment.</p> <p>14. <input type="checkbox"/> A substitute specification.</p> <p>15. <input type="checkbox"/> A change of power of attorney and/or address letter.</p> <p>16. <input checked="" type="checkbox"/> Other items or information:</p> <p>PCT Chapter II Demand Express Mail Certificate Check in the amount of \$1230.00</p>					

U.S. APPLICATION NO (if known, see 37 CFR 1.5)		INTERNATIONAL APPLICATION NO <b>PCT/GB99/03731</b>		ATTORNEY'S DOCKET NUMBER <b>2001-0878-RI</b>	
17. <input checked="" type="checkbox"/> The following fees are submitted: <b>BASIC NATIONAL FEE (37 CFR 1.492 (a) (1) - (5)) :</b> Neither international preliminary examination fee (37 CFR 1.482) nor international search fee (37 CFR 1.445(a)(2)) paid to USPTO and International Search Report not prepared by the EPO or JPO ..... \$970.00 International preliminary examination fee (37 CFR 1.482) not paid to USPTO but International Search Report prepared by the EPO or JPO ..... \$840.00 International preliminary examination fee (37 CFR 1.482) not paid to USPTO but international search fee (37 CFR 1.445(a)(2)) paid to USPTO ..... \$690.00 International preliminary examination fee paid to USPTO (37 CFR 1.482) but all claims did not satisfy provisions of PCT Article 33(1)-(4) ..... \$670.00 International preliminary examination fee paid to USPTO (37 CFR 1.482) and all claims satisfied provisions of PCT Article 33(1)-(4) ..... \$96.00 <b>ENTER APPROPRIATE BASIC FEE AMOUNT =</b>				CALCULATIONS PTO USE ONLY	
Surcharge of \$130.00 for furnishing the oath or declaration later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(e)).				\$	n/a
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	29 - 20 =	9	X \$18.00	\$	162.00
Independent claims	4 - 3 =	1	X \$78.00	\$	78.00
MULTIPLE DEPENDENT CLAIM(S) (if applicable)			20	+	\$260.00
<b>TOTAL OF ABOVE CALCULATIONS =</b>				\$	1230.00
Reduction of 1/2 for filing by small entity, if applicable. A Small Entity Statement must also be filed (Note 37 CFR 1.9, 1.27, 1.28).				\$	n/a
<b>SUBTOTAL =</b>				\$	1230.00
Processing fee of \$130.00 for furnishing the English translation later than <input type="checkbox"/> 20 <input type="checkbox"/> 30 months from the earliest claimed priority date (37 CFR 1.492(f)).				\$	n/a
<b>TOTAL NATIONAL FEE =</b>				\$	1230.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property				+	\$ n/a
<b>TOTAL FEES ENCLOSED =</b>				\$	1230.00
				Amount to be:	\$
				refunded	
				charged	\$
a. <input checked="" type="checkbox"/> A check in the amount of \$ <u>1230.00</u> to cover the above fees is enclosed.					
b. <input type="checkbox"/> Please charge my Deposit Account No. _____ in the amount of \$ _____ to cover the above fees. A duplicate copy of this sheet is enclosed.					
c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>50-0789</u> . A duplicate copy of this sheet is enclosed.					
<b>NOTE:</b> Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.					
SEND ALL CORRESPONDENCE TO: Mark J. Burns, Esq. 1130 TCF Tower 121 South Eighth Street Minneapolis, MN 55402				 SIGNATURE: Mark J. Burns NAME <u>46,591</u> REGISTRATION NUMBER	



## UNITED STATES PATENT AND TRADEMARK OFFICE

Commissioner for Patents, Box 100  
United States Patent and Trademark Office  
Washington, D.C. 20231  
www.uspto.gov

U.S. APPLICATION NO.	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/831681	WIGMORE	A 2001-0878.OR

MARK J BURNS  
1130 TCF TOWER  
121 SOUTH EIGHTH STREET  
MINNEAPOLIS MN 55402

INTERNATIONAL APPLICATION NO.

PCT/GB99/03731

I.A. FILING DATE	PRIORITY DATE
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09 NOV 99

11 NOV 98

DATE MAILED:

12 JUN 2001

**NOTIFICATION OF ACCEPTANCE OF APPLICATION UNDER 35 U.S.C. 371  
AND 37 CFR 1.494 OR 1.495**

1. The applicant is hereby advised that the United States Patent and Trademark Office in its capacity as ☐ a Designated Office (37 CFR 1.494), ☒ an Elected Office (37 CFR 1.495), has determined that the above-identified international application has met the requirements of 35 U.S.C. 371, and is **ACCEPTED** for national patentability examination in the United States Patent and Trademark Office.

2. The United States Application Number assigned to the application is shown above and the relevant dates are:

10 MAY 2001

10 MAY 2001

DATE OF RECEIPT OF  
35 U.S.C. 371(c)(1), (c)(2) and (c)(4) REQUIREMENTSDATE OF RECEIPT OF ALL  
35 U.S.C. 371 REQUIREMENTS

A Filing Receipt (PTO-103X) will be issued for the present application in due course. **THE DATE APPEARING ON THE FILING RECEIPT AS THE "FILING DATE" IS THE DATE ON WHICH THE LAST OF THE 35 U.S.C. 371 REQUIREMENTS HAS BEEN RECEIVED IN THE OFFICE. THIS DATE IS SHOWN ABOVE.** The filing date of the above-identified application is the international filing date of the international application (Article 11(3) and 35 U.S.C. 363). Once the Filing Receipt has been received, send all correspondence to the Group Art Unit designated thereon.

3. ☒ A request for immediate examination under 35 U.S.C. 371(f) was received on 10 MAY 2001 and the application will be examined in turn.

4. The following items have been received:

- ☒ U.S. Basic National Fee.
- ☒ Copy of the international application.
- ☐ Translation of the international application into English.
- ☒ Oath or Declaration of inventors(s).
- ☐ Copy of Article 19 amendments. ☐ Translation of Article 19 amendments into English.

The Article 19 amendments ☐ have ☐ not been entered.

- ☒ The International Preliminary Examination Report in English and its Annexes, if any.
- ☐ Copy of the Annexes to the International Preliminary Examination Report (IPER).
- ☐ Translation of Annexes to the IPER into English.

The Annexes ☐ have ☐ not been entered.

- ☐ Preliminary amendment(s) filed \_\_\_\_\_ and \_\_\_\_\_.
- ☐ Information Disclosure Statement(s) filed \_\_\_\_\_ and \_\_\_\_\_.
- ☐ Assignment document.
- ☐ Power of Attorney and/or Change of Address.
- ☐ Substitute specification filed \_\_\_\_\_.
- ☐ Indication of Small Entity Status.
- ☒ Priority Document.
- ☒ Copy of the International Search Report ☒ and copies of the references cited therein.
- ☐ Other:

RECEIVED  
DEC 18 2002  
TECH CENTER 1600/2900